

## REMARKS

Applicant has cancelled claim 25, amended claims 26, 28-29 and 35, and added new claims 45-48. Claims 24 and 26-48 are currently pending in this application.

In the Office Action, the Examiner indicated that claims 27-34 and 37-43 would be allowable if they are rewritten in independent form. Applicant gratefully acknowledges the Examiner's indication of allowable subject matter.

The Examiner rejected claims 24-26, 35, 36 and 44 under 35 U.S.C. Section 102(b) as being anticipated by Teirstein (U.S. Patent No. 5,779,666). Applicant traverses the rejection.

An important feature of Applicants' invention is the manner in which the two one-way valves 19 and 18 operate to assure proper and safe operation of the system. When the pump 13 is drawing in contrast medium from the bag 11, it is important that the valve 19 automatically open and the valve 18 automatically close. The contrast medium will flow into the pump and nothing will flow upstream from the connecting tube 22. Thus nothing will flow upstream from the vascular system to which the apparatus is connected.

It is further important that when the pump 13 delivers the contrast medium from the pump to the vascular system, that the valve 19 automatically close. The contrast medium is not returned to the bag 11 and the valve 18 will automatically open so that the contrast medium can be delivered through the connecting tubular member 22 to the vascular system.

As persons of ordinary skill in the art will appreciate, it is particularly advantageous that these two valves 19 and 18 automatically open and close in response to the differential pressures to which they are subjected so that this operation proceeds with assurance and with safety. Therefore, no error can be made by a human operator in opening or closing any valves. In order for this objective to be met and the functions that are provided by these valves 19 and 18 to occur, there should be no ports other than the ports 24 and 27 that are controlled by the valves 19 and 18 which are in communication with the inlet-outlet port 25 to which the pump 13 is connected.

If there are any other ports in the manifold defined by the inlet port 24 (controlled by valve 19), the outlet port 27 (controlled by valve 18) and the inlet-outlet port 25 (connected to the pump 13) an automatic, safe and assured system would not function properly.

All independent claims recite this automatic valve feature. For example, claim 24 recites: the delivering step including: suctioning at said first inlet-outlet port by the pump to cause said first one-way valve to automatically open, allowing flow of contrast medium from said bag into the pump, and to cause said second one-way valve to automatically close, preventing fluid flow upstream from said connecting tubular member into the pump, and exerting positive pressure at said first inlet-outlet port from the pump to cause said second one-way valve to automatically open, allowing fluid flow from said pump into said tubular member, and to cause said first one-way valve to automatically close, preventing upstream fluid flow to the source.

By contrast, the valves 44, 46 of Teirstein are coupled to the manifold 16 and are in addition to the inlet valve 42 and outlet port 48 (see col. 4, lines 58-64).

These multiple valves 42, 44, 46 and 48 are manual valves that must be operated by hand during the purge operation and during delivery of the contrast medium. Teirstein even admits that the purging operation is a very time consuming operation precisely because all of the valves must be manually adjusted (See col. 5, lines 5-25). More important than the time consuming nature, however, the manual nature of the Teirstein system can be very dangerous when delivering a pressurized contrast media such as CO<sub>2</sub> because one mistake in adjusting the valves can cause the dumping of excess pressurized contrast media to the patient. As disclosed in the background section of the present application at page 2, lines 11-15, liters of CO<sub>2</sub> can be delivered to the patient in less than a minute due to the high pressure of CO<sub>2</sub>, which could be fatal. Teirstein neither teaches nor suggests an automatic contrast media delivery as recited in claim 24.

For the similar reasons as discussed above with respect to claim 24, applicants submit that independent claims 35, 45 and 48 are also patentable. Dependent claims 26, 36, 44 and 46-47 are also patentable by virtue of their dependency from independent parent claims 24, 35 and 45.

Based upon the above amendments and remarks, applicants respectfully request reconsideration of this application and its early allowance. Should the Examiner feel that a

telephone conference with applicants' attorney would expedite prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,

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### MARKED-UP CLAIMS

Please cancel claim 25 without prejudice or disclaimer.

Please amend the claims as follows:

24. (Amended) A method for supplying a contrast medium to a patient's vascular system comprising:

(a) providing a flexible bag filled with contrast medium at essentially atmospheric pressure;

(b) operatively connecting said flexible bag to the patient's vascular system via a gas transfer system, said gas transfer system including:

a dual check valve adapted to be connected to a lower pressure source of contrast medium, said dual check valve having a first inlet port, a first outlet port and a first inlet-outlet port,

said dual check valve containing a first one-way valve at said first inlet port automatically responsive to the relatively low pressure at said first inlet-outlet port to permit downstream fluid flow and to prevent upstream fluid flow,

said dual check valve containing a second one-way valve at said first outlet port automatically responsive to the relatively high pressure at said first inlet-outlet port to permit downstream fluid flow and to prevent upstream fluid flow,

said first inlet-outlet port in communication with said first and second one-way valves and adapted to be connected to a pump, and

a connecting tubular member having an upstream and a downstream end, said upstream end in communication with said first outlet port of said dual check valve;

(c) purging said gas transfer system of air; and

(d) delivering said contrast medium from said flexible bag through said gas transfer system to the patient's vascular system, the delivering step including:

suctioning at said first inlet-outlet port by the pump to cause said first one-way valve to automatically open, allowing flow of contrast medium from said bag into the pump,

and to cause said second one-way valve to automatically close, preventing fluid flow upstream from said connecting tubular member into the pump, and

exerting positive pressure at said first inlet-outlet port from the pump to cause said second one-way valve to automatically open, allowing fluid flow from said pump into said tubular member, and to cause said first one-way valve to automatically close, preventing upstream fluid flow to the source.

26. (Amended) The method of Claim [25] 24, wherein said gas transfer system further comprises a first stopcock upstream of said first inlet port of said dual check valve to turn flow from the source on and off.

28. (Amended) The method of Claim [25] 24, wherein said gas transfer system further comprises a stopcock on said downstream end of said tubular member to turn flow into the catheter on and off.

29. (Amended) The method of Claim [25] 24, wherein said gas transfer system further comprises an in-line check valve connected to said downstream end of said tubular member, wherein said in-line check valve has a second inlet port in which said tubular member is connected, a second inlet-outlet port adapted to be connected to an ancillary pump, and a second outlet port connected to a first stopcock which is connected to the catheter.

35. (Amended) [The method of Claim 24, wherein said gas transfer system comprises] A method for supplying a contrast medium to a patient's vascular system, comprising:

(a) providing a flexible bag filled with contrast medium at essentially atmospheric pressure;

(b) operatively connecting said flexible bag to the patient's vascular system via a gas transfer system, said gas transfer system including:

a first dual check valve adapted to be connected to a lower pressure source of said contrast medium, said first dual check valve having a first inlet port, a first outlet port and a first inlet-outlet port,

said first dual check valve containing a first one-way valve at said first inlet port automatically responsive to the relatively low pressure at said first inlet-outlet port to permit downstream fluid flow and to prevent upstream fluid flow,

said first dual check valve containing a second one-way valve at said first outlet port automatically responsive to the relatively high pressure at said first inlet-outlet port to permit downstream fluid flow and to prevent upstream fluid flow,

said first inlet-outlet port in communication with said first and second one-way valves and adapted to be connected to a pump,

a connecting tubular member having an upstream and a downstream end, said upstream end in communication with said first outlet port of said first dual check valve,

[suction at said first inlet-outlet port by the pump causing flow of medium from whatever source is coupled to said first inlet port through said first one-way valve into the pump, said second one-way valve preventing fluid flow upstream from said connecting tubular member into the pump, ]

[positive pressure at said first inlet-outlet port from the pump causing fluid flow through said second one-way valve and said first outlet port into said tubular member, said first one-way valve preventing upstream fluid flow to the source,] and

a third one-way valve in communication with said downstream end of said tubular member to permit downstream fluid flow from said tubular member and to prevent upstream fluid flow in said tubular member;

[wherein said gas transfer system delivers contrast medium at low pressure to a catheter for delivery to the patient's vascular system]

(c) purging said gas transfer system of air; and

(d) delivering said contrast medium from said flexible bag through said gas transfer system to the patient's vascular system, the delivering step including:

suctioning at said first inlet-outlet port by the pump to cause said first one-way valve to automatically open, allowing flow of contrast medium from said bag into the pump, and

to cause said second one-way valve to automatically close, preventing fluid flow upstream from said connecting tubular member into the pump, and

exerting positive pressure at said first inlet-outlet port from the pump to cause said second and third one-way valves to automatically open, allowing fluid flow from said pump into said tubular member, and to cause said first one-way valve to automatically close, preventing upstream fluid flow to the source.

Please add the following new claims.

--45. (New) A method for supplying a contrast medium to a patient's vascular system, comprising:

connecting a source filled with a contrast medium to a patient's vascular system via a gas transfer system, the gas transfer system including:

a pump;

a dual check valve having an inlet port coupled to the source, an outlet port and an inlet-outlet port coupled to the pump;

a tubular member having an upstream end connected to the outlet port and a downstream end connectable to a catheter;

a first one-way valve coupled to the inlet port to control the flow of the contrast medium from the source; and

a second one-way valve coupled to the outlet port to control the flow of the contrast medium to the catheter for delivery to the patient's vascular system;

purging the gas transfer system of air, the purging step including:

drawing the contrast medium from the source to the pump, the drawing step:

automatically opening the first one-way valve, allowing the contrast medium from the source to flow into the pump; and

automatically closing the second one-way valve, preventing upstream fluid flow from the tubular member into the pump;

exerting positive pressure in the pump, the exerting step:

automatically opening the second one-way valve, allowing the contrast medium in the pump to flow into the tubular member; and

automatically closing the first one-way valve, preventing upstream fluid flow from the pump into the source.

46. (New) The method according to claim 45, further comprising:  
coupling the catheter to the tubular member; and  
repeating the steps of drawing and exerting to deliver the contrast medium from the source to the patient's vascular system.

47. (New) The method according to claim 45, further comprising coupling an in-line check valve having a third one-way valve to the downstream end of the tubular member, wherein during the drawing step, the third one-way valve automatically closes to prevent air from entering the tubular member and during the exerting step, the third one-way valve automatically opens to allow the contrast medium in the tubular member to escape into the air.

48. (New) A method for supplying a contrast medium to a patient's vascular system, comprising:

connecting a source of a contrast medium to a patient's vascular system via a gas transfer system;

purging a gas transfer system of air, the gas transfer system including a check valve having an inlet port, an outlet port and an inlet-outlet port;

drawing the contrast medium from the inlet port coupled to the source into a pump coupled to the inlet-outlet port, the drawing step:

automatically opening a first one-way valve coupled to the inlet port, allowing the contrast medium from the source to flow into the pump; and

automatically closing a second one-way valve coupled to the outlet port, preventing upstream fluid flow from a tubular member coupled to the outlet port; and

exerting positive pressure from the pump to:

automatically open the second one-way valve, allowing the contrast medium in the pump to flow into the tubular member; and



automatically close the first one-way valve, preventing upstream fluid flow from the pump into the source.--